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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,327	05/15/2002	Jay M Meythaler	UAB-15102/22	3596

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GIFFORD, KRASS, SPRINKLE, ANDERSON &
CITKOWSKI, P.C.
P.O. BOX 7021
TROY, MI 48007-7021

EXAMINER

CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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08/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/049,327	Applicant(s) MEYTHALER ET AL.	
	Examiner KATHRIEN CRUZ	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,29,34-36 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,29,34-36 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/13/2008 has been entered.

Action Summary

The rejection of claims 1, 7, 29, 34-36 and 40 under 35 U.S.C. 103(a) as being unpatentable over Grilli et al. (WO 98/20864), in view of Bakhshi et al. (Journal of Neuro-Oncology, 26,133-9), in view of Myseros et al. (The rationale for glutamate antagonists in the treatment of traumatic brain injury, Ann NY Acad Sci, 1995, 765:262- 271) and further in view of McGeer et al. (USPN 5192753) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed 03/13/2008 have been fully considered but they are not persuasive. Applicants essentially argue that the teachings of Grilli et al. (WO 98/20864) of NSAIDs do not include choline magnesium trisalicylate. The examiner respectfully disagrees.

NSAID is the genus of which choline magnesium trisalicylate does in fact belong within this group. And furthermore, at the time of the invention all NSAID were assumed to have the same properties because McGeer teaches that Alzheimer disease can be effectively treated with any drug of the NSAID class (column 2, lines 53-55).

Applicants' request that patentability weight be granted for claim language "non-inhibitory of platelets so as to reduce the inflammation associated with the neurotrauma". This is found not persuasive because non-inhibitory of platelets is a property of an NSAID such as choline magnesium trisalicylate. And normally patentability is NOT given to properties of composition. As stated in the previous office action dated 11/13/2007, that it is known to administer the same compositions as instantly claimed, the compositions would obviously be non-inhibitory of platelets. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ43 (CCPA 1963).

Applicants' argue that McGeer et al demonstrates an equivalence between choline magnesium trisalicylate and acetylsalicylic acid as well as salicylate are equivalence. However, McGeer states that they are in a genus of arylcarboxylic acids and that these NSAIDs use singularly or in combination and will differ in dosage (column 2, lines 7-10) to effectively inhibit prostaglandin synthesis but not to induce unwanted side effects. It is **EXTREMELY** well known that aspirin causes blood thinning and may increase bleeding, however, having the anti-inflammatory effect is important in treating neurotrauma as taught by Grilli et al. Grilli et al teach that sodium salicylate and salicylamide are specifically taught as useful agents having anti-inflammatory properties.

Applicants' argue that Bakhshi et al in teaching the administration of CNS drugs via intrathecal catheter does not reach to the pending claims in terms of delivery of choline magnesium trisalicylate. This is found not to be persuasive because Bakhshi et al. teach that intrathecal administration for the treatment of Alzheimer's disease is well known in the art. Bakhshi also discloses that the use of implantable pumps for CNS drug infusion for the treatment of Alzheimer's disease remain a viable option if the appropriate drug regime is found (page 137, third paragraph). This regime would include choline magnesium trisalicylate.

Applicant's argue that Myseros et al is lacking a teaching relevant to the treatment of neurotrauma or neuronal injury. This is found to not to be persuasive because Myseros et al teaches that prevention and/or treatment of glutamate neurotoxicity with glutamate antagonists results in improvement in both mortality and morbidity. Myseros et al also teaches that excessive release of excitatory amino acids (EAAs) as an important cause of brain damage, especially in acute ischemia and chronic neurodegeneration (summary). Therefore, Myseros et al. further teaches NSAIDs taught by Grilli et al. are useful in treating neurotrauma associated with traumatic brain injury. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/Jennifer Kim/
Primary Examiner, Art Unit 1617